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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Thomas RICHARDSON et al.

Serial No.: 10/058,835 Group Art Unit: 1635

Filed: January 30, 2002 Examiner: Tracy A. Vivlemore

For: METHODS FOR SUSTAINED RELEASE LOCAL DELIVERY OF DRUGS FOR ABLATION OF UNWANTED TISSUE

RESPONSE TO REQUIREMENT FOR RESTRICTION

Commissioner for Patents
P.O. Box 1450
ALEXANDRIA, VA 22313-1450

SIR:

In response to the Office Action mailed June 2, 2004, and the restriction requirement set forth therein, Applicants hereby elect Group I, claims 1-3, 5-12, 14-17 and 24-26, drawn to the embodiment of the invention wherein removing undesired fat tissue by injection of a controlled release formulation of TNF-alpha. The election is made with traverse for the reasons set forth below. Applicants reserve the right to file one of more divisional applications directed to the non-elected subject matter.

The claims are alleged to be restrictable into 12 groups. This despite the fact that there is only one independent claim, claim 1, and all other claims depend upon claim 1. And further despite the fact that all the claims – and all the groups of invention set out in the Office Action – are directed to the same independent and distinct method of "eliminating or reducing normal but undesired tissue in a patient which comprises administering a controlled release formulation to the patient by injection at a local area containing the undesired tissue such that the undesired tissue in the local area is eliminated or reduced, said formulation comprising a substance which

eliminates or prevents formation of the cells of the undesired tissue, said substance being provided in a controlled release carrier." Applicants respectfully urge that in this situation there is no proper basis for a restriction requirement. At most, the claims could be subject to an election of species requirement. The claims are all species of the same generic unitary invention.

The basis alleged to support the restriction is that the inventions are "unrelated." Applicants fail to understand how it can be alleged that the invention are "unrelated" when they are all species of the same genus recited in claim 1. The inventions are, unquestionably, related to each other. In fact, they are not different inventions but different embodiments of the same invention.

It is further alleged in the Office Action that the different species of the invention have different modes of operation because different compounds are used to effect the same result of "eliminating or reducing normal but undesired tissue." Under this theory, every species of every genus would always be restricted from each other. This is not proper restriction practice nor should it be. The use of MPEP §806.04 and 808.1 as the basis for this restriction is not proper and, even if proper, is not properly applied. The section of MPEP §806.04 which is referred to in the Office Action states, in whole:

> (A) Two different combinations, not disclosed as capable of use together, having different modes of operation, different functions or different effects are independent. An article of apparel such as a shoe, and a locomotive bearing would be an example. A process of painting a house and a process of boring a well would be a second example.

This is clearly not the applicable section for the instant claims. There are not "two different combinations" involved here and the instant facts are nowhere near the type of situation of the examples given. Instead, MPEP §806.04 specifically addresses the genus-species situation

separately, stating:

> Where inventions as disclosed and claimed are both (A) species under a claimed genus and (B) related, then the question of restriction must be determined by both the practice applicable to election of species and the practice applicable to other types of restrictions such as those covered in MPEP § 806.05 -§ 806.05(i). If restriction is improper under either practice, it should not be required.

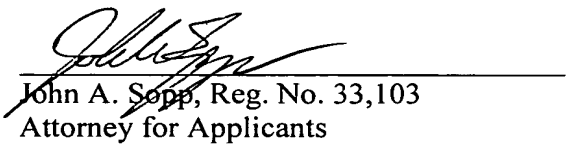
It is noted that none of the situations under MPEP § 806.05 -§ 806.05(i) apply here. Thus, only election of species practice would be proper, as stated above.

Applicants accordingly strongly urge that the restriction requirement here be withdrawn in full. By making a 12-way restriction here, the USPTO is trying to force applicants to file 12 separate applications (and pay 12 sets of filing fees, prosecution fees, issue fees and maintenance fees) for examination of what is clearly a single inventive concept. If the inventive concept is considered too broad for a single examination, the USPTO's election of species and Markush-practice set up to address such situations should be used. In this connection, applicants disagree that the invention is particularly broad. The claims are not merely to any method of "eliminating or reducing normal but undesired tissue in a patient" but only those methods which comprise the clearly defined and distinct steps of "administering a controlled release formulation to the patient by injection at a local area containing the undesired tissue such that the undesired tissue in the local area is eliminated or reduced, said formulation comprising a substance which eliminates or prevents formation of the cells of the undesired tissue, said substance being provided in a controlled release carrier."

For all of the above reasons, withdrawal of the restriction requirement is earnestly requested.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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JAS:rrt